



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nobuyuki Miyasaka et al. Art Unit : 1647
Serial No. : 10/088,661 Examiner : Cherie Michelle Woodward
Filed : July 19, 2002 Conf. No. : 2830
Title : THERAPEUTIC AGENT FOR RHEUMATISM P21CIP1

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the Action mailed February 14, 2006, applicants elect the invention of Group I, claims 9 and 13. The election is made with traverse, for the reasons set forth herein.

Since the instant application was filed under 35 U.S.C. § 371, the PCT rules regarding unity of invention apply. PCT Rule 13.2 stipulates that the requirement of unity of invention shall be fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding "special technical features." The expression "special technical features" is defined as those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

At page 2 of the Action, the Examiner alleges that "Groups I and [sic, to] VI do not relate to a single general inventive concept under PCT Rule 13.1. The Examiner asserts that the inventions lack the same or corresponding special technical features because

... claim 1¹ lacks novelty under PCT Article 33(2) as being anticipated by Sugiyama *et al.*, Localisation of apoptosis and expression of apoptosis related proteins in the synovium of patients with rheumatoid arthritis. Ann Rheum Dis 1996 July 55(7):442-9. Sugiyama *et al.*, disclose a apoptosis specific morphology and expression of p21/Cipl in rheumatoid arthritis synovial tissue.

Applicants respectfully traverse. The Sugiyama reference indeed discloses the expression of p21/Cipl in synovial tissues of rheumatoid arthritis patients. However, it does not

¹ Applicants assume that the Examiner meant "claim 9," as claim 1 has been cancelled.

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teach the idea that p21/Cipl can be used to treat or prevent aberrant growth or inflammation of synovial tissue and to inhibit the expression of inflammatory cytokines in synovial tissue. Thus, Applicants believe that the invention of claim 9 is novel and that the inventions of Groups I to VI do share a technical feature that contributes over Sugiyama et al. Therefore, Groups I to VI should be examined together.

In addition, Applicants respectfully submit that the Examiner's application of the test of "unity of invention" is inconsistent with the guideline provided in the MPEP. The Examiner denies unity of invention among Groups IV and VI. However, the administrative instructions regarding unity of invention asserts that unity of invention should be considered only in relation to the independent claims. Quoting from the MPEP, "Instructions Concerning Unity of Invention," Appendix AI, Annex B, Part I (emphasis added):

Unity of invention has to be considered in the first place ***only in relation to the independent claims*** in an international application and not the dependent claims. By "dependent" claims is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.). If the independent claims avoid the prior art and satisfy the requirement of unity of invention, ***no problem of lack of unity arises in respect of any claims that depend on the independent claims***. In particular, it does not matter if a dependent claim itself contains a further invention.

In the present application, the claims of Group II-IV and VI all depend (either directly or indirectly) on claim 9 of Group I. Therefore, for this reason alone, the restriction between Groups I-IV and VI is improper.

Applicant : Nobuyuki Miyasaka et al.
Serial No. : 10/088,661
Filed : July 19, 2002
Page : 3 of 3

Attorney's Docket No.: 14875-103US1 / C1-109PCT-
US

Summary


In conclusion. Applicants respectfully request reconsideration of the restriction requirement, and submit that Groups I-VI, or at least Groups I-IV and VI (i.e., claims 9-16 and 25) should be examined in the same application.

A check for the extension of time fee is enclosed. Please apply any additional charges or credits to Deposit Account No. 06-1050, referencing attorney docket no. 14875-103US1.

Respectfully submitted,

Date: _____

August 3, 2006



Janice L. Kugler
Reg. No. 50,429

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906